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Remarks

Status of the Application and the Present Response

Prior to entry of the present Response, claims 1-9, 11-13, 15-19, and 22-74 were pending in the application, with claims 34-74 being withdrawn from the application as directed to non-elected inventions. With entry of the instant response, claims 15-19, 29-32, 42, and 60 have been canceled without prejudice. In addition, claims 1, 2, 6, 28, 40, 56, 63, 64, 67, and 71 have been currently amended.

Specifically, claims 1, 56, 63, 64, 67, and 71 have been amended to clarify that the reporter gene and the protein solubility responsive promoter are present in a recombinant nucleic acid. Further, these claims have been amended to specify that the solubility responsive promoter is isolated from *Escherichia coli*. Claim 28 has been amended to specify that the host cell is an *E. coli* cell. Claims 2, 6, and 40 have been amended to replace the recital of "at least 75%" of sequence identity with the recital of "at least 95%" of sequence identity. Support for these amendments is replete in the Specification, e.g., at page 17, lines 1-9; and page 18, lines 1 and 19.

The amendments made herein do not introduce new matter. Unless otherwise indicated, the claim amendments have been made to improve clarity or to expedite prosecution of the subject application, and should not be construed as acquiescence of any ground of rejections.

The instant Office Action maintained the rejection of the pending claims as allegedly failing to comply with the written description requirement. In addition, claims 1, 4, 5, 8, 11, 13, 15-18, 22 and 28-32 were rejected under 35 U.S.C. § 102(b). The following remarks address these and other issues raised in the instant Office Action.

Double Patenting

Claim 1 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting in view of claim 3 of co-pending application 10/127,078 and claim 10 of co-pending application 09/991,499.

Applicants thank the Examiner for clarification on the existence of co-pending application 09/991,499. As indicated previously, Applicants with address

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these provisional rejections once claims in the co-pending applications have been issued.

Rejection under 35 U.S.C. § 112 - Written Description

The instant Office Action maintained the rejection of claims 1, 2, 4-6, 8, 9, 11-13, 15-19 and 22-33 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. It was alleged in the Office Action that the specification does not provide adequate written description for the recitation of "prokaryotic solubility responsive promoters" recited in the claims. Applicants respectively disagree with the reasoning set forth in the instant Office Action. However, to expedite prosecution of the subject application, Applicants have presently further amended the claims. The claims now only recite protein solubility promoters isolated from *E. coli*.

As acknowledged by the Examiner in the Office Actions, Applicants have provided a reasonable number of representative protein solubility response promoters that are obtained from *E. coli*. The subject specification has undoubtedly provided sufficient description of protein solubility response genes and promoters from *E. coli* (e.g., at page 18, lines 1-10; and pages 32-34). Accordingly, Applicants respectfully request that the instant rejection be withdrawn.

Rejection under 35 U.S.C. § 112

Claim 19 was rejected because it depends from a canceled claim. This rejection is rendered moot by the cancellation of claim 19 in the instant response.

Rejection under 35 U.S.C. § 102

Claims 1, 4, 5, 8, 11, 13, 15-18, 22 and 28-32 were rejected as allegedly unpatentable over Allen et al., J. Bacteriol. 174: 6938 (1992). It was stated in the Office Action that Allen et al. discloses a host cell comprising a nucleic acid that comprises a prokaryotic protein solubility responsive promoter operably linked to a reporter gene and a target polypeptide-expressing nucleic acid that comprises a polynucleotide that encodes a target polypeptide heterologous to the host cell. The Office Action then concluded that Allen et al. anticipates the subject invention.

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In response, Applicants have amended claim 1 to clarify that the protein solubility responsive promoter and the reporter gene are present in a recombinant nucleic acid. Other relevant claims in the non-elected inventions have been similarly amended. These amendments make clear that the nucleic acid of the present invention which expresses the reporter gene under the control of the protein solubility responsive promoter is recombinantly produced. By contrast, the host cell reported in Allen et al. merely contains endogenous "reporter genes" (*ibpA* or *ibpB*) under the control of their native promoters. Thus, Allen et al. do not teach a host cell comprising a recombinant reporter nucleic acid as recited in the presently claimed invention. Accordingly, the pending claims are novel and patentable over Allen et al. Withdrawal of the instant rejection is therefore respectfully requested.

Rejoinder of Previously Withdrawn Claims

Pursuant to MPEP § 821.04, withdrawn process claims as a result of restriction requirement which depend from or otherwise include all the limitations of an allowable product claim should be rejoined. In the instant application, claims 37-41, 43-59, and 61-72 have been previously withdrawn by the Examiner as directed to non-elected inventions. These process claims depend from or contain all the limitations of claim 1. Therefore, because claim 1 is now in condition for allowance, Applicants respectfully request that these claims be rejoined and examined in the present application.

Conclusion

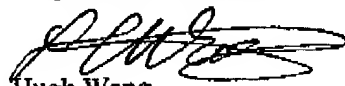
In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

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If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1539.

Respectfully submitted,


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